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GianCarlo Moschini
Iowa State, moschini@iastate.edu

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GianCarlo Moschini
moschini@iastate.edu
515-294-5761

The recent European Union (EU) draft legislation on labeling and tracing all food and feed consisting of, containing, or produced from genetically modified (GM) organisms has the potential to significantly affect long-run U.S. agricultural exports to Europe. For the last three years, a de facto moratorium has halted approval of new GM varieties in the EU. Whereas the proposed new EU legislation may help resolve this impasse, the details of this draft legislation are raising considerable concern in the U.S. agricultural community and, if approved, are likely to give rise to a serious trade dispute within the World Trade Organization.

It seems that this EU proposal marks an increase in the international divergence in the way new biotechnology products are being regulated. Some have suggested that differing GM product regulations in the United States and in the EU can be traced back to the EU reliance on the "precautionary principle." Whereas the EU has embraced such a concept as the guiding principle in developing its new regulations on GM food, the United States has resisted explicitly recognizing it.

Background

The principle of precautionary action is rooted in German environmental law and was first applied internationally at a 1987 London conference dealing with the protection of the North Sea. This concept was adopted in the 1992 United Nations Conference on Environment and Development, where it was succinctly described in one of the principles of the Rio Declaration: "Lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation." The Biosafety Protocol agreed to in Montreal in 2000, the first international agreement with provisions aimed at regulating trade of GM products, also explicitly appeals to the precautionary principle. These applications of the precautionary approach dealt with environmental risks, but the EU Commission made a substantial extension of its scope last year by adopting it to deal more generally with risk to " …the environment, human, animal and plant health," effectively expanding the use of this principle to include food safety.

The extension of the precautionary principle to deal with food safety, and in particular its use to regulate GM food, has been very controversial. Some have charged that the principle is unscientific. Others have argued that it is a logical fallacy to rely on this principle to establish the safety of new products because it amounts to imposing an impossible burden of proof. This conclusion is based on interpreting the precautionary principle to mean that a new product or a new technology should not be approved as long as there is the possibility of some harm being done, that is, effectively demanding a conclusive proof of zero risk. But this rendition of the precautionary principle is untenable.

Rational Choice under Risk

How should we deal with the risks that inevitably are associated with a new technology? Suppose we need to decide between allowing a new GM variety and not allowing it. When the choice involves genuine uncertainty (something is not known for sure), decision theory, as developed by economists and statisticians, emphasizes the crucial aspects of trading off benefits and costs across possible "states of the

world." If for all possible contingencies the new variety gives only positive outcomes, then the choice is obvious. But typically that is not the case, and we must trade off net positive benefits that accrue when everything turns out smoothly with the net costs that accrue when a negative outcome actually materializes. This trade-off requires that we know the size of net benefits or costs in each possible state of the world and the probability of that contingency to arise (so that, for example, a catastrophic outcome that is believed possible only with a very small probability can still have a substantial impact on choice). Furthermore, this trade-off depends on the risk tolerance of the decisionmaker. This much is clear for individual choices: one person's desired portfolio allocation between stocks and cash is not necessarily optimal for another person.

The problem is more complex when we deal with risk trade-offs not for an individual but for society. But the essence of the problem is the same. What is the role of science in this framework? Quite clearly, science has a lot to offer in identifying the various possible outcomes of an action and the probability that can be associated with each possible outcome. But science is not of much help in deciding what the optimal level of risk exposure should be (just as an economist cannot tell you how much of your portfolio to put in stocks). That is why risk regulation has traditionally distinguished between "risk assessment" and "risk management." Risk assessment is the technical step, and relies heavily on scientific evidence, whereas risk management is the policy stage, where a decision is made on how much risk can be tolerated (conceivably in exchange for expected net benefits).

Does application of the precautionary principle necessarily lead to a drastically different way of dealing with and regulating risk? No, it does not. The precautionary principle should be interpreted as a tool for risk management, the policy stage of choosing the optimal risk exposure. Its basic tenet is that, when some uncertainty exists about the outcomes of an action, this uncertainty must be factored into the choice problem. This is exactly what decision theory mandates! Viewed in this light, the precautionary principle is less objectionable, but it is also not as novel and is perhaps redundant. Indeed, even when the precautionary principle is not invoked explicitly, regulatory actions aimed at risk can be construed as being consistent with it. For example, the 1998 U.S. decision to withhold approval of StarLink maize for human consumption (because of the possibility, to this day unverified, that its particular Bt protein could be an allergen) arguably can be characterized as a textbook application of the precautionary principle.

The Real Issues

Differing and incompatible national regulations for GM food could prove crippling to the commodity-based international trading system for agricultural products. Harmonization of such regulations is imperative if the heralded gains from biotechnology innovations in agriculture are to be realized. A rational and credible process for dealing with the potential risks of these new technologies is, of course, crucial. In this context, an ideological opposition to the precautionary principle is misplaced. Reliance on the precautionary principle need not bias public choices against new technologies when it is seen in the context of risk management (as opposed to risk assessment). The unresolved issue, perhaps, is how to make the precautionary principle operational in a transparent way, so that it can be translated into effective policy choices that strike an optimal trade-off between benefits and risks of new technologies.

If the EU policies on GM products are perceived as too cautious, it may be because either "excessive" risk aversion is being built into regulations, or incorrect presumptions on possible outcomes and their probabilities are being used. In the latter case, science can be of considerable help in dispelling misconceptions, and more scientific evidence on various implications of GM products is needed. In the former case, the question to ask is, why pick on GM products? If very different risk standards are being used with respect to GM products (relative to traditionally bred varieties, for example), then this point needs to be attacked directly, not peripherally. Regulating risk requires that we understand what to be afraid of, and to what degree, but there is no need to be afraid of the precautionary principle. ◆

GianCarlo Moschini is professor of economics and Pioneer Chair in Science and Technology Policy.